

SEP 25 2003
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

DAVIS et al.

Atty. Ref.: 620-148

Serial No. 09/897,412

Group: 1647

Filed: July 3, 2001

Examiner: Nichols, C.

For: USE OF SECRETIN-RECEPTOR LIGANDS IN
TREATMENT OF CYSTIC FIBROSIS (CF) AND CHRONIC
OBSTRUCTIVE PULMONARY DISEASE (COPD)

* * * * *

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

September 25, 2003

Sir:

INFORMATION DISCLOSURE STATEMENT

- ☐ 1. **PTO-1449 Pursuant to 37 CFR 1.97(b)**
[within 3 months of filing or prior to 1st Office Action on the merits]
N/C
- ☐ 2.(a) **Statement Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
N/C
- ☒ 2.(b) **Fee Payment Pursuant to 37 CFR 1.97(c)**
[before Final Office Action or Allowance (requires Rule 97(e)
Statement or Rule 17(p) fee)]
\$180.00
- ☐ 3. **Pursuant to 37 CFR 1.97(d)**
[after Final Office Action or Allowance (requires Rule 97(e)
Statement and Rule 17(p) fee), but before final fee payment]
\$180.00

The following are submitted in the above-identified application in compliance with
37 C.F.R. §§ 1.97 and 1.98:

ALL INFORMATION CONTAINED HEREIN IS UNCLASSIFIED

DATE 10/13/01 BY 1016

769634

- ☒ 4. A list of documents on Form PTO-1449 together with copies of each identified document and a translation or a concise explanation of each non-English language document (such as a Search Report) is enclosed herewith.

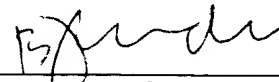
This paper is submitted in accordance with:

- ☐ 5. 37 CFR 1.97(b): [within 3 months of filing or prior to 1st Office Action]
- ☒ 6. 37 CFR 1.97(c): [before Final Office Action or Allowance, whichever is earlier]; and
- ☐ a) The required Statement made in item 8 below; or
- ☒ b) The \$180.00 fee specified in 37 CFR §1.17(p) for submission of this Information Disclosure Statement is authorized in item 9 below.
- ☐ 7. 37 CFR §1.97(d): [after Final Office Action or Allowance (requires Rule 97(e) Statement and Rule 17(p) fee), but before final fee payment]; and
- ☐ a) The fee (\$180.00) required by 37 CFR §1.17(p) is submitted herewith; and
- ☐ b) The required Statement is stated in item 8 below.
- ☐ 8. Statement under 37 CFR 1.97(e)
- ☐ a) The undersigned attorney of record hereby certifies under 37 C.F.R. §1.97(e) that each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement (each item contained in this IDS was the first citation of that item by a foreign patent office in a counterpart foreign application which occurred no more than three months prior to the filing of this IDS); or
- ☐ b) No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement, after making reasonable inquiry, no item of information contained in this Statement was known to any individual designated in 37 CFR §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

- ☒ 9. Please charge all deficiency fees associated with the submission of this Information Disclosure Statement and any other fees applicable to this application to Deposit Account No. 14-1140. An original and one (1) copy of this document are enclosed.

Respectfully submitted,
NIXON & VANDERHYE P.C.

By: _____



B. J. Sadoff

Reg. No. 36,663

1100 North Glebe Road, 8th Floor
Arlington, VA 22201-4714
Telephone: (703) 816-4000
Facsimile: (703) 816-4100

**INFORMATION DISCLOSURE
CITATION**

(Use several sheets if necessary)

Atty. Docket No.

Serial No.

620-148**09/897,412**

Applicant

DAVIS et al.

Filing Date

Group

July 3, 2001**1647**

SEP 7 5 2001

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	6,020,314	2/2000	McMichael			

FOREIGN PATENT DOCUMENTS

DOCUMENT	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
WO 97/33616	9/1997	PCT			
WO 98/52593	11/1998	PCT			
WO 99/64059	12/1999	PCT			

OTHER DOCUMENTS (including Author, Title, Date, Pertinent pages, etc.)

	Gespach et al. Peptides, Vol. 7, Suppl. 1, 155-163 (1986) "Secretin Receptor Activity in Rat Gastric Glands. Binding Studies. cAMP Generation and Pharmacology"
	Mutt et al. Eur. J. Biochem. 15, (1970) 513-519 "Structure of Porcine Secretin"
	Mutoh et al. Proc. Natl. Acad. Sci. Vol. 94, 3560-3564 (1997) Biochemistry "The basic helix-loop-helix transcription factor BETA2/NeuroD is expressed in mamalian enteroendocrine cells and activates secretin gene expression"
	Mutoh et al. Genes & Development 12:820-830 (1998) "The basic helix-loop-helix protein BETA2 interacts with p300 to coordinate differentiation of secretin-expressing enteroendocrine cells"
	Chang et al. The J. of Biological Chemistry, Vol. 274, No. 16, 10758-10764 (1999) "Porcine Pancreatic Phospholipase A ₂ Stimulates Secretin Release from Secretin-producing Cells"
	Chang et al. Am. J. Physiol. 275 (Gastrointest. Liver Physiol. 38) G192-G202 (1998) "Modulation of secretin release by neuropeptides in secretin-producing cells"
	Sexton. Current Opinion in Drug Discovery and Development, Vol. 2(5), 440-488 (1999) "Recent advances in our understanding of peptide hormone receptors and RAMPS"
	Stern et al. J. Royal College of Physicians of London, Vol. 33, No. 5, 434-439 (1999) "The pathogenesis of cystic fibrosis and progress towards gene therapy"
	Cross et al et al. Life Sciences, Vol. 29, 895-902 (1981) "Synthesis, Biological and Immunochemical Properties o Analogues of Secretin and Vasoactive Intestinal Peptide (VIP): The Vasectrins
	Fortner et al. Am. J. Physiol. Lung Cell Mol Physiol 280: L334-L341 (2001) "Chloride channel function is linked to epithelium-dependent airway relaxation"
	Wolf et al Chest, 89, 3, 327-330 (1986) "Demonstration of calcitonin and calmodulin by immunoperoxidase in the cystic fibrosis lung"
	Chang et al. AJP-Gastrointestinal and Liver Physiology Abstract Vol. 279, Issue 2, G295-G303 (2000) "Cellular mechanism of sodium oleate-stimulated secretion of cholecystokinin and secretin"
	Xue et al. Medline Abstract. Dig Dis Sci 38:344-352 (1993) "Characterization of secretin release in secretin cell-enriched preparation isolated from canine duodenal mucosa"

*Examiner

Date Considered

Examiner Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to application